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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark R. McCormick

Date: October 28, 1999

Serial No.: 08/724,631

Examiner: G. Kunz

Filed: October 1, 1996

Group Art Unit: 1211

For: METHOD FOR PRECIPITATING NUCLEIC ACID WITH VISIBLE CARRIER

File No.: 700399.90053

DECLARATION OF LISA JOHNSON UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington DC 20231

Dear Sir:

I, Lisa Johnson, declare and state that:

1. I am the director of business development for Novagen, Inc. ("Novagen"), assignee of the above-noted patent application. I have held this position for 2 years. Prior to that, I was business manager at Novagen.

2. Novagen is a small biotechnology company with a modest annual marketing budget. Novagen's primary sales and marketing tools are its product catalog and a periodic customer newsletter ("inNovations") that features technical advice and reports on uses of products sold by Novagen. Novagen also strategically purchases space in relevant trade journals and advertises in direct mail card decks distributed to potential customers, such as researchers on a journal's mail list.

3. I have reviewed the Office Action mailed by the U.S. Patent and Trademark Office on May 28, 1999 and understand that the Examiner has rejected the pending method and product claims as obvious over a paper by Gaillard et al. in view of a patent to Arbige or a patent to Burrows et al. The Examiner has not considered the substantial commercial success of Novagen's co-precipitant product that is within the scope of the claims now pending. This

Declaration is presented so that the Examiner will have an opportunity to consider that commercial success when reconsidering the merits of the patent application.

4. An embodiment of the claimed composition is manufactured and has been sold since 1996 by Novagen as Pellet Paint co-precipitant which can be used in the claimed method. The product is also sold as SeeDNA co-precipitant by OEM Customer Amersham Life Science ("Amersham") that purchases the product for resale from Novagen.

5. Novagen's marketing of the Pellet Paint co-precipitant to molecular biologists and others who prepare nucleic acid samples in the course of their work is consistent with the company's other marketing efforts, and is in no way extraordinary. Attached to this Declaration as Exhibits 1 - 9 are materials by Novagen and it's OEM customer Amersham that describe the Pellet Paint / SeeDNA co-precipitant.

6. Exhibit 1 is page 75 of the 1996-1997 Novagen catalog.

7. Exhibit 2 is page 101 of the 1997-98 Novagen catalog.

8. Exhibit 3 is page 113 of the 1998-1999 Novagen catalog.

9. Exhibit 4 (inNovations (Issue No. 4a) (May 1996)) features an article about Pellet Paint on pages 10 and 11.

10. Exhibit 5 (inNovations (Issue No. 5) (August 1996)) features an article on use of Pellet Paint as a co-precipitant in the ribonuclease protection assay.

11. Exhibit 6 is the Novagen 1998-1999 catalog.

12. Exhibit 7 is a one-third page advertisement that typically appears in about one technical journal per quarter.

13. Exhibit 8 is a card advertisement from a card deck that has been distributed on several occasions. An interested customer can return a card to a vendor to receive further information about an advertised product.

14. Exhibit 9 is pages 9 and 10 of Life Science News (Issue 20) published by Amersham.

15. Despite Novagen's modest advertising budget, Pellet Paint co-precipitant has been a notable success in the marketplace. In terms of unit sales, Pellet Paint sells better than any

other of the almost 900 products available for purchase in the 1998-1999 Novagen catalog. In terms of dollar sales, Pellet Paint is Novagen's fourth best selling retail (non-OEM) product and the fifth best selling product in total dollar sales. Pellet Paint co-precipitant sales have increased approximately ten percent per year since 1996 and are expected to exceed one hundred thousand dollars in 1999.

16. Soon after it was introduced, Pellet Paint was embraced by noted private and public research institutions, within and outside the United States, and has received positive reviews in the technical literature of the trade. *See, e.g.*, Hengen, P., TIBS 21 (June 1996), cited by the Examiner in Paper No. 7, and Taggart, E.W., 36 J. Clin. Microbiol. 3408-9 (Nov. 1998), attached to this Declaration as Exhibit 10.

17. While a Novagen card deck promotion typically nets about one hundred, or at most about two hundred, responses, the first Pellet Paint card yielded more than twelve hundred responses to Novagen and far exceeded any other comparable response rate for the company. Each subsequent card deck promotion has yielded about five hundred inquiries.

18. Pellet Paint co-precipitant is now so well-received and well-known in the marketplace that in three short years it has become the calling card in laboratories for the company's sales force that provides a basis for introducing customers and potential customers to other Novagen products.

19. I was unaware of any dye-labeled polymeric carrier product commercially available for use in nucleic acid precipitation prior to Novagen's introduction of Pellet Paint co-precipitant. I was likewise aware of no commercially available dye-labeled glycogen product prior to Pellet Paint.

20. In 1997, Ambion introduced GlycoBlue co-precipitant, a blue dye-labeled glycogen that competes directly with Pellet Paint co-precipitant in the marketplace. Attached to this Declaration as Exhibit 11 is Ambion TechNotes (v. 4, no. 4, p. 7) (1997) which describes the GlycoBlue product. Attached to this Declaration as Exhibit 12 is page 118 of the Ambion 1999 catalog which also describes the GlycoBlue product.

21. I hereby declare that all statements made herein of my own knowledge are

true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated this 28th day of October, 1999.

Lisa Johnson